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for example, to begin the automated fill process. As shown in FIG. 47, the control system 700 may actuate the peristaltic pump 200 to operate in reverse while opening the valve 265 to allow a predetermined volume of the dilution solution, as set by the user, to flow from the dilution container 260 into the bulk product vial 100.

As shown in FIG. 48, the valve 265 may be closed to the dilution container 260 and nitrogen forced through the system to purge any remaining dilution solution from the peristaltic tubing leading to the bulk product vial 100. In doing so, nitrogen may be bubbled through the diluted radiopharmaceutical product in the bulk product vial 100 before exiting through the vent filter, for example, further helping to mix the diluted product.

In accordance with another aspect of the present invention, rather than using nitrogen to clear the lines, for example, the peristaltic pump 200 may be operated to return a small amount of the diluted product back to the CAV container 1502. The pump 200 may then be reversed again to return the small amount of diluted product from the CAV container 1502 back to the bulk product vial 100. Thus, any small amount of liquid that may be left remaining in the CAV container 1502 or the lines from the CAV container 1502 to the dispensing manifold assembly 300 will be diluted, rather 25 than concentrated.

As shown in FIGS. 49 and 50, the control system 700 may operate the pump 200 to fill the manifold tubes 310 with the diluted product up to the furthest final product vial 400 or 405. The control system 700 may then begin filling the vials from right to left, for example, starting with the sterility vial 450, followed by the quality check vial 482, and then each of the final product vials 400 and 405. Although described in a particular order herein, the control system 700 may be configured through user input via the computer system 1200 to 35 fill the vials in any order.

As shown in FIG. **51**, excess diluted product in the bulk product vial **100**, along with excess diluted product in the peristaltic tubing and the manifold tubes **310**, for example, may be purged using nitrogen and collected in a final product 40 vial **405** connected to the manifold tube **310** furthest from the pump **200**. As shown in FIGS. **52-55**, the fill process may be completed by purging any diluted product remaining in the lines to the vials, for example, preferably beginning with the vial farthest away from the pump and continuing with each 45 closer vial until all of the vials have been purged.

In accordance with another aspect of the present invention. as shown in FIG. 56, a rinse, such as water, or any other suitable cleansing fluid, may be provided from the synthesis unit to further clean the disposables of possible radioactive 50 residue. The rinse may be delivered from the synthesis unit through the line 565 and deposited into the CAV container 1502. Once the rinse is delivered to the CAV container 1502, the user may select a "Start Rinse" command, for example, to begin the rinse process. As shown in FIGS. 57 and 58, the 55 control system 700 may actuate the peristaltic pump 200 to operate in a reverse direction in order to transfer the rinse from the CAV container 1502 to the bulk product vial 100. As shown in FIG. 59, with the CAV container 1502 and the fluid lines between the CAV container 1502 and the bulk product 60 vial 100 thus rinsed, the peristaltic pump 200 may be operated to draw the rinse from the bulk product vial 100 and force the rinse through the manifold tubes 310 to the waste receptacle (not shown). In accordance with yet another aspect of the present invention, as shown in FIG. 60, the peristaltic pump 200 may continue to operate in order to draw in atmospheric air, for example, through the vented bulk product vial 100 and

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pump the air through the lines and the manifold tubes 310 until all of the rinse is deposited into the waste receptacle.

In accordance with yet another aspect of the present invention, as shown in FIGS. 61-65, the remaining dilution solution in the dilution container 260 may be used to perform another rinse of the disposable components. As shown in FIG. 61, the valve 265 may be opened and the peristaltic pump 200 operated to pull the remaining dilution solution from the dilution container 260 into the bulk product vial 100. Once the remaining dilution solution is in the bulk product vial 100, as shown in FIG. 62, the valve 265 may be closed to the dilution container 260, the valve 266 may be opened to allow fluid communication between the bulk product vial 100 and the CAV container 1502, and the peristaltic pump 200 may be operated in reverse to pull the dilution solution from the bulk product vial 100 and pump the dilution solution into the CAV container 1502.

As shown in FIG. 63, once the dilution solution has been pumped into the CAV container 1502, the process may be reversed by reversing the direction of the pump 200 and the dilution solution transferred back to the bulk product vial 100 from the CAV container 1502. With the fluid path between the bulk product vial 100 and the CAV container 1502 thus rinsed, the valves 265 and 266 may be opened to allow fluid flow through the manifold tubes 310. As shown in FIG. 64, the dilution solution may then be pumped out of the bulk product vial 100 and through the manifold tubes 310 to the waste receptacle (not shown). As shown in FIG. 65, the peristaltic pump 200 may continue to operate in order to draw in atmospheric air, for example, through the vented bulk product vial 100 and pump the air through the system until all or substantially all of the dilution solution is forced from the manifold tubes 310 and into the waste receptacle (not shown).

As described previously, the vials may then be removed from the system 10 for transport in a shielded container to the appropriate location for testing and/or use in a procedure. The disposable components of the system 10 may be removed and discarded according to the proper protocol and the system prepared for another run.

The previous description is provided to enable any person skilled in the art to practice the various exemplary implementations described herein. Various modifications to these variations will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other implementations. All structural and functional equivalents to the elements of the various illustrious examples described throughout this disclosure that are known or later come to be known to those of ordinary skill in the art are expressly incorporated herein by reference.

The invention claimed is:

- 1. A closed path vial fill system, comprising:
- a bulk product vial containing a bulk product;
- a first tube element inserted into a peristaltic pump, wherein the first tube element is coupled with the bulk product vial;
- a dispensing manifold assembly coupled with the first tube element;
- at least one final product vial coupled to the dispensing manifold assembly;
- a valve disposed between the peristaltic pump and the dispensing manifold assembly, the valve having a first position and a second position; and
- a dilution container having a dilution solution, wherein the dilution container is coupled to the valve,
- wherein in the first position, the valve allows fluid to flow from the dilution container to the bulk product vial,